REMARKS

Claim 1 has been amended to recite a "powder composition comprising at least one fat-soluble vitamin dispersed in a matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof, wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm) and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight." Support for this amendment is found in the specification at, for example, page 10, lines 20-27, in original claim 14, and particularly at page 23, lines 19-24. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claim 14 has been amended to recite "[a] powder composition according to claim 1 wherein the composition comprises from about 10 to about 30% by weight of a fat-soluble vitamin and from about 60 to 85% by weight of a matrix component, based on the total weight of all the components present in the composition." Support for this amendment is found in the specification at, for example, page 10, lines 20-27, original claim 14, and particularly at page 23, lines 19-24. (*Id.*).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments are respectfully solicited.

Rejections Under 35 USC § 103

Claims 1, 7-15, and 17 were rejected under 35 USC §103(a) as being unpatentable over Stroh *et al.*, WO 99/42134 ("Stroh"). (Paper No. 20070522 at 2).

For the reasons set forth below the rejection, respectfully is traversed.

Stroh discloses a spray dried powder containing edible oil droplets comprising 40 to 90 % edible oil and 10 to 60 % gelatin, wherein the edible oil droplets have an average diameter of ≤0.8 µm. (Claim 1). Stroh further discloses that the "preferred oil-droplet size is 0.05 to 0.8µ, more preferably of 0.1 to 0.4µ, [and] most preferably of 0.25 to 0.35 µ." (Page 7, lines 6-7). Stroh is ***silent*** regarding a powder composition having a fat-soluble vitamin in the amount of from about 10% to about 30% by weight.

In making the rejection, the Examiner asserted that Stroh "teaches ... spray dried tablettable powders comprising high edible oil loadings based on non-hydrolyzed gelatin and a method of making such spray dried tablettable powders, with a droplet size of less than 0.8 microns (page 5-6), preferably 0.05 to 0.8 microns (page 6, L 6-8)." (Paper No. 20070522 at 2). The Examiner further asserted that Stroh "teaches [that] edible oils include vitamins such as vitamin A, Vitamin E etc (page 6, L 23-42)" and that Stroh "teaches 40%-90% edible oil and 10-60% gelatin in the composition, which percentages overlap with the claimed percentages of vitamin and matrix (claim 14)." (*Id.*).

The Examiner acknowledged, however that "[w]hile [Stroh] teaches the same fat-soluble vitamins, same protein and the droplet size of the fat-soluble materials

in the range of 0.05 to 0.8 microns (50 to 800 nm), [Stroh] does not teach the exact range of the claimed powders." (*Id.* at 2-3).

The Examiner then concluded that "it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the size of the droplets or vitamin powders and still achieve the same high loading of oil soluble vitamins so as to prepare a tablettable preparation" and "optimizing the amounts and ratios of vitamin and gelatin to arrive at the claimed ratios would have been within the scope of a skilled artisan." (*Id.* at 3).

With a view towards furthering prosecution, independent claim 1 has been amended to recite "[a] powder composition comprising at least one fat-soluble vitamin dispersed in a matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof, wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm) ***and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight***."

It is well settled that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984): If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to do what the Applicants have done. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (April 30, 2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify a document must be thorough and searching. *See also* Examination Guidelines for Determining Obviousness, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

Initially, we respectfully note that the rejection is devoid of a proper §103 analysis. All that is there is a conclusory statement that "it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the size of the droplets or vitamin powders and still achieve the same high loading of oil soluble vitamins so as to prepare a tablettable preparation." (Paper No. 20070522 at 3). What the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosure of Stroh to arrive at the claimed composition. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty.*,

Ltd., 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, "to establish *prima facie* obviousness of a claimed invention, ***all claim limitations must be taught or suggested by the prior art***." MPEP § 2143.03 (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)) (emphasis added).

Assuming *arguendo* that "one of ordinary skill in the art at the time of the instant invention [could] optimize the size of the droplets or vitamin powders and still achieve the same high loading of oil soluble vitamins so as to prepare a tablettable preparation," which is *not* conceded, such a modification does not produce amended claim 1, from which claims 7-15 and 17 depend. (Paper No. 20070522 at 3). The rejection does not - and cannot - identify where in Stroh there is disclosed that a "fat-soluble vitamin is present in the powder composition in the form of solid droplets having

an average diameter of about 80 to about 120 nanometers (nm) ***and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight***" as recited in amended claim 1.

It is respectfully submitted that Stroh does not disclose or suggest currently amended claim 1. Stroh reports high oil loading, tablettable powders. This is evident from Stroh's title and disclosure. Stroh's title is "Spray-Dried Powders with **High Edible-Oil Loadings** Based on Non-Hydrolyzed Gelatin and a Method of Making Such Spray-Dried Tablettable Powders". (emphasis added). Stroh states in the specification:

> Surprisingly, Applicants have improved on the art of **high oil loading tablettable powders**. Specifically, Applicants's high oil loading tablettable powders are less greasy than currently available products; have better tabletting properties; and **the oil loading can be as high as 90% to deliver more active ingredient in a smaller tablet**.
>
> (Stroh, page 3, lines 9-14) (emphasis added).
>
> Stroh further reports that the concentration of edible oil in the powder is at least 40% and preferable ranges are also reported. (Page 8, lines 10-12). Stroh states:
>
> **Said edible oils are present at levels of 40 to 90%**, more preferably 50 to 80%, and most preferably 65 to 80%.
>
> (Id.) (emphasis added).

Stroh discusses "processing advantages" in that '[a]t higher loadings of the active ingredient, less carrier is required which leads to cost savings." (Page 3, lines 16-19). Thus, Stroh aims to provide tablettable powders with high oil loadings as high as 90% to deliver more active ingredient in a smaller tablet. Along with Stroh's teaching of a high concentration of edible oil, Stroh reports the use of a relatively low concentration of gelatin.

Stroh also states that the most preferred oil droplet size for their high edible oil loading powder is 0.25 to 0.35 μm (page 7, line 7). This is further illustrated by Examples 3-19. All of the emulsions according to the Examples of Stroh contain droplets having diameters above 200 nm.

An object of the present invention, on the other hand, is to provide a powder composition of fat-soluble vitamins without affecting the optical clarity of a resulting beverage and without causing ringing around the sides of the container. The presently claimed powder composition achieves good tabletting properties. And, in a beverage produced from the claimed powder, turbidity is minimized and good colloidal stability results. There is no indication that Stroh seeks to achieve all of these objects, nor how to accomplish such objectives, even if it was desired to accomplish them.

The presently claimed powder composition comprises an amount of fat-soluble vitamin (from about 10% to about 30% by weight) which is in contravention to the specific teachings of Stroh of providing "high oil loading tablettable powders" in which edible oils are present at levels of 40 to 90%.

Furthermore, Stroh fails to teach, suggest or provide motivation for the presently claimed subject matter, i.e., a "fat-soluble vitamin [that] is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm) and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight."

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1, 3-7, 9, 11-15, and 17 were rejected under 35 USC §103(a) as being unpatentable over Stroh in view of Stein *et al.*, EP 0 937 412 ("Stein"). (Paper No. 20070522 at 3).

The rejection respectfully is traversed. At the outset it is noted that all arguments made in this paper concerning Stroh are readopted and reasserted with respect to this rejection.

Stein discloses "a continuous process for the preparation of a pulverous carotenoid, retinoid or natural colourant preparation, wherein the active ingredient is finely divided ...." (Stein, Abstract). The process includes the steps of:

> a) forming a suspension of the active ingredient in a water-inmiscible organic solvent optionally containing an antioxidant and/or an oil,
> b) feeding the suspension of step a) to a heat exchanger and heating said suspension to 100-250°C, whereby the residence time in the heat exchanger is less than 5 sec,
> c) rapidly mixing the solution of step b) at a temperature in the range of 20-100°C with an aqueous solution of a swellable colloid optionally containing a stabilizer,
> d) removing the organic solvent and
> e) converting the dispersion of step d) into a pulverous preparation.
>
> (Col. 2, lines 3-16.)

The "finely divided" starting material is said to be of "a particle size of less than 1.5 micron, preferably less than 1 micron, more preferably less than 0.4 micron." (*Id.*, lines 18-21.) Stein further discloses that the "swellable colloid" can include gelatin, carbohydrates, dextrin, pectin, gun arabic, octenylbutanedioate amylodextrin, milk

proteins, and vegetable protein, or mixtures thereof. (Col. 3, lines 2-8.) Stein also discloses that powders formed from the compositions are soluble in cold water and provide coloration. (*See*, Examples 1-5.)

In making the rejection, the Examiner asserted that Stroh "teach[es] gelatin as a base for the preparation of spray-dried tablets." (Paper No. 20070522 at 3).

The Examiner acknowledged, however, that Stroh "does not teach the claimed polysaccharides of the instant gums." (Id.).

To fill the acknowledged gap, the Examiner relied on Stein for "teach[ing] finely divided pulverous carotenoids preparations formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, rapidly mixing with a swellable colloid." (Id.). The Examiner further asserted that Stein "teaches the particle size such as 213 nm, 225 nm or 400 nm," and that Stein "teaches gelatin, starch, gums, pectin etc (col. 3, L 1-7) and in particular, gum arabic of claims 3-6." (Id.).

The Examiner then summarily concluded that "[i]t would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the tablettable powders of [Stroh] by incorporating colloids such as polysaccharide gums such as those taught by [Stein] because [Stein] suggests colloids such as gelatin and gums as equivalent in preparing vitamin powder preparations." (Id.). The Examiner also concluded that "absent any unexpected advantage, it would have been within the scope of a skilled artisan to optimize the amounts of vitamins and colloids, based on the colloid employed, so as to prepare vitamin powder preparations with the claimed particle sizes." (Id. at 3-4).

With a view towards furthering prosecution, independent claim 1 has been amended to recite "[a] powder composition comprising at least one fat-soluble vitamin dispersed in a matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof, wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm) ***and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight***."

It is well settled that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to do what the Applicants have done. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (April 30, 2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify documents must be thorough and searching. And, as is well settled, the teaching,

motivation, or suggestion to combine "***must be based on objective evidence of record***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also* Examination Guidelines for Determining Obviousness, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

The rejection is devoid of a proper §103 analysis. All that is there are two conclusory statements: (1) "[i]t would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the tablettable powders of [Stroh] by incorporating colloids such as polysaccharide gums such as those taught by [Stein] because [Stein] suggests colloids such as gelatin and gums as equivalent in preparing vitamin powder preparations" and (2) "it would have been within the scope of a skilled artisan to optimize the amounts of vitamins and colloids, based on the colloid employed, so as to prepare vitamin powder preparations with the claimed particle sizes." (Paper No. 20070522 at 3). What the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosure of Stroh with Stein to arrive at the claimed composition. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to

establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

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Assuming *arguendo* that "[i]t would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the tablettable powders of [Stroh] by incorporating colloids such as polysaccharide gums such as those taught by [Stein] because [Stein] suggests colloids such as gelatin and gums as equivalent in preparing vitamin powder preparations," which is ***not*** conceded, such a modification does not produce amended claim 1, from which claims 3-7, 9, 11-15 and 17 depend. (Paper No. 20070522 at 3). The rejection does not - and cannot - identify where in Stroh or Stein there is disclosed that a "fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about

80 to about 120 nanometers (nm) ***and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight***" as recited in amended claim 1.

It is respectfully submitted that Stroh does not disclose or suggest currently amended claim 1. Stroh reports high oil loading, tablettable powders. This is evident from Stroh's title and disclosure. Stroh's title is "Spray-Dried Powders with High Edible-Oil Loadings Based on Non-Hydrolyzed Gelatin and a Method of Making Such Spray-Dried Tablettable Powders". (emphasis added). Stroh states in the specification:

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An object of the present invention, on the other hand, is to provide a powder composition of fat-soluble vitamins without affecting the optical clarity of a resulting beverage and without causing ringing around the sides of the container. The presently claimed powder composition achieves good tabletting properties. And, in a beverage produced from the claimed powder, turbidity is minimized and good colloidal stability results. There is no indication that Stroh seeks to achieve all of these objects, nor how to accomplish such objectives, even if it was desired to accomplish them.

The presently claimed powder composition comprises an amount of fat-soluble vitamin (from about 10% to about 30% by weight) which is in contravention to the specific teachings of Stroh of providing "high oil loading tablettable powders" in which edible oils are present at levels of 40 to 90%.

Furthermore, Stroh fails to teach, suggest or provide motivation for the presently claimed subject matter, i.e., a "fat-soluble vitamin [that] is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm) and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight."

In attempting to fill the gaps of Stroh, the Examiner has cited Stein. The Examiner has not identified, however, where in Stein there is disclosed a powder composition with emulsion forming compositions in combination with a fat-soluble vitamin in the form of droplets having a diameter of 80-120 nm, as claimed. Moreover,

the rejection identified nothing in Stein that even suggests the claimed powder composition. At best, Stein discloses a particle size of 150-400 nm. This is 125% to 500% of the claimed particle size.

Applicants also refer the Examiner to the previously submitted Rule 132 declaration of Dr. Hermann Stein (the "Stein Declaration") (Exhibit C) that accompanied the Submission Under 37 CFR 1.114: Response to Final Office Action dated March 24, 2005. The Stein declaration shows that particles of the claimed size could not have been produced using the method of Stein. In the declaration, Dr. Stein, a co-inventor of the subject matter disclosed in Stein, states that he and his co-inventors attempted to produce the smallest possible particle size. (Stein Declaration, ¶ 6.) The particles disclosed in Example 5 of Stein were the smallest particles that Dr. Stein and his co-inventors were able to produce at that time. (Id., ¶¶ 6-7.)

According to Dr. Stein, one could not have predicted that the process of the claimed invention would produce significantly smaller particle sizes than the methods of Stein. (Id., ¶ 8.) Moreover, Dr. Stein concludes, based on his knowledge of the compositions and methods of Stein and his experience in this area, that one of skill in the art at the time of the present invention familiar with the disclosure of Stein could not have produced particles of the size claimed. (Id., ¶ 7.)

Even if the combination of references cited by the Examiner were proper, which Applicants do not concede, Stroh in view of Stein fails to teach, suggest or provide motivation for the presently claimed subject matter, i.e., a "fat-soluble vitamin [that] is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm) and wherein the fat-

soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight."

In view of the foregoing, it is respectfully submitted that the rejection has been overcome. Accordingly, withdrawal of the rejection is respectfully requested.

We also note that both rejections under § 103(a) are also devoid of any discussion of the dependent claims. Accordingly, the record lacks any evidence that the Examiner individually considered the dependent claims. It is axiomatic, however, that a dependent claim is not *per se* unpatentable by a document that allegedly makes unpatentable the base claim. Accordingly, "[e]xaminers are reminded that a dependent claim is directed to a combination including everything recited in the base claim and what is recited in the dependent claim. It is this combination that must be compared with the prior art, exactly as if it were presented as one independent claim." MPEP § 608.01(n) (8th ed., Rev. 5, Aug. 2006, pp. 600-91). This the Examiner has not done. Accordingly, both rejections are also factually and legally deficient as to the dependent claims. For this additional reason, both rejections should be withdrawn as to the dependent claims.

Application No.: 09/726,880
Response Dated: November 26, 2007
Response to Office Action of: May 25, 2007

For the reasons set forth above, withdrawal of the rejections and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 26, 2007.

Eileen M. Ebel, Reg. No. 37, 316

Respectfully submitted,

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